

### **REMARKS**

Claims 1-6, 8-18 and 21-27 were pending in this application. Claims 4-6, 8-12, 15-18 and 25-27 have been withdrawn by the Examiner as being drawn to non-elected inventions. Upon allowance of the pending claims, withdrawn claims that depend from or otherwise require all the limitations of the allowable claim(s) should be rejoined in accordance with the provisions of MPEP § 821.04.

Claims 1, 22, 23 and 24 have been amended to clarify certain embodiments of the presently claimed invention. Support for the amendments can be found in the specification at, *inter alia*, page 5, lines 13-17, 18-22, 23-27, and 28-32, respectively.

Claims 9, 12, 15 and 17 have been amended to correct a few minor editorial and/or typographical errors.

No new matter has been added. Upon entry of these amendments, claims 1-6, 8-18 and 21-27 will be pending.

#### **I. THE CLAIM REJECTIONS UNDER 35 U.S.C. § 103 SHOULD BE WITHDRAWN**

Claims 1-3, 13, 14 and 21-24 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kaddurah-Daouk (U.S. Patent No. 5,998,458, "Kaddurah-Daouk") in view of Meisner (U.S. Patent No. 4,772,591, "Meisner"), Grant *et al.* (U.S. Patent No. 5,888,553, "Grant"), Beale (U.S. Patent No. 5,756,469, "Beale '469"), and Beale *et al.* (U.S. Patent No. 5,716,926, "Beale '926"). In response to the Amendment filed on May 8, 2006, the Examiner alleges that Applicants' arguments regarding the amount used in the prior art are not persuasive since they are for treatment of diseases other than a bone or cartilage condition and/or for agents other than creatine pyruvate. (See Office Action, ¶6) The Examiner also alleges that the cited references meet the limitation "in need thereof." (See Office Action, ¶7). Moreover, the Examiner alleges that the claims are directed to an old and well known ultimate utility which is inherently disclosed in the prior art. (See Office Action, ¶8). Furthermore, the Examiner alleges that the fact that Applicants have recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. (See Office Action, ¶9). Finally, the Examiner alleges that hindsight reconstruction is necessary and proper, and insists that there is suggestion and motivation in the cited reference to combine the references. (See Office Action, ¶¶10 and 11). For the following reasons, Applicants disagree.

**1. The Legal Standard**

**a. Claim Construction**

“If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is ‘necessary to give life, meaning, and vitality’ to the claim, then the claim preamble should be construed as if in the balance of the claim.” *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 U.S.P.Q.2d 1161, 1165-66 (Fed. Cir. 1999); see also *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333, 68 U.S.P.Q.2d 1154, 1158 (Fed. Cir. 2003), and MPEP § 2111.02. In *Jansen*, the court held that a claim preamble which sets forth the objective of the method, and the claim’s recitation of a patient or a human “in need” gives life and meaning to the preamble’s statement of purpose. *Jansen v. Rexall Sundown*, 342 F.3d. at 1333. In considering the effect of the preamble in a method of treatment claim, the court in *Jansen* held that a patent claiming method “for treating or preventing” particular condition to be performed on “human in need thereof” requires that human know that he or she was in need of treatment or prevention of said particular condition. *Id.* at 1334.

**b. Obviousness**

A finding of obviousness under 35 U.S.C. § 103 requires a determination of the scope and the content of the prior art, the differences between the invention and the prior art, the level of the ordinary skill in the art, and whether the differences are such that the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. *Graham v. Deere*, 383 U.S. 1 (1966). The relevant inquiry is whether the prior art suggests the invention, and whether one of ordinary skill in the art would have had a reasonable expectation that the claimed invention would be successful. *In re O'Farrell*, 853 F.2d 894, 7 U.S.P.Q.2d 1673 (Fed. Cir. 1988); *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Both the suggestion of the claimed invention and the expectation of success must be in the prior art, not in the disclosure of the claimed invention. *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1532 (Fed. Cir. 1988). In determining obviousness, “the inquiry is not whether each element existed in prior art, but whether the prior art made obvious the invention as a whole for which patentability is claimed.” *Hartness International Inc. v. Simplimatic Engineering Co.*, 819 F.2d 1100, 2 U.S.P.Q.2d 1826 (Fed. Cir. 1987).

Further, an obviousness rejection cannot be based on inherent disclosure in a prior art reference. The Court of Customs and Patent Appeals has stated that “the inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.” *In re Spormann*, 363 F.2d 444, 448, 150 U.S.P.Q. 449, 452 (C.C.P.A. 1966).

## **2. The Meaning of the Amended Claims**

As amended, claims 1, 22, 23 and 24 require that the methods be practiced with the intent to achieve the objective stated in the respective preamble, namely the objectives of treating at least one bone or cartilage condition (claim 1); promoting growth and mineralization of bone or cartilage cells and tissues (claim 22); improving acceptance and osseous integration of bone implants (claim 23); and accelerating healing of a defect in bone or cartilage tissue caused by trauma or surgery (claim 24). *Jansen v. Rexall*, 342 F.3d at 1333.

Specifically, amended claim 1, which recites “[a] method of treating at least one bone or cartilage condition” in “an animal in need of such treatment,” requires that the animal know that it was desirous of being treated for said bone or cartilage condition.

Amended claim 22, which recites “[a] method of promoting growth and mineralization of bone or cartilage cells and tissues” in “a subject in need of such promotion,” requires that the subject know that he or she was desirous of having said bone or cartilage cell or tissue growth and mineralization.

Amended claim 23, which recites “[a] method of improving acceptance and osseous integration of bone implants” in “a subject in need of such improvement,” requires that the subject know that he or she was desirous of having said improved acceptance and osseous integration of bone implants.

Amended claim 24, which recites “[a] method for accelerating healing...[of] a defect in bone or cartilage tissue caused by trauma or surgery” in “a subject in need thereof,” requires that the subject know that he or she was desirous of having said accelerated healing.

Accordingly, a reference (or references) which fails to teach or suggest the administration of the recited amount of creatine pyruvate or an analogue thereof for the recited, intended purpose of treating at least one bone or cartilage condition (claim 1); promoting growth and mineralization of bone or cartilage cells and tissues (claim 22); improving acceptance and osseous integration of bone implants (claim 23); or accelerating

healing of a defect in bone or cartilage tissue caused by trauma or surgery (claim 24), does not render obvious the claimed methods. *Jansen v. Rexall*, 342 F.3d at 1333.

**3. The Amended Claims Are Patentable Over The Cited References**

**a. Amended Claim 1**

Regarding amended claim 1, none of the references disclose, teach or suggest the use of the recited amount of creatine pyruvate to treat at least one bone or cartilage condition in a subject who is desirous of said treatment. While Kaddurah-Daouk discloses osteoporosis and osteoarthritis as two examples of disorders which relate to weight regulation (see col. 2, lines 48-49), the Examiner admits that Kaddurah-Daouk does not teach the employment of creatine pyruvate, or the particular amount administered, for treating osteoporosis or osteoarthritis. (See Office Action, ¶4). Meisner, Grant, Beale '469, and Beale '926 do not cure the deficiencies of Kaddurah-Daouk, because none of these references disclose, teach or suggest the use of creatine pyruvate, much less the use of creatine pyruvate at the recited amount to treat at least one bone or cartilage condition in a subject who is desirous of said treatment; and thus, do not provide the missing suggestion.

Nonetheless, the Examiner alleges that it is *prima facie* obvious to combine two compounds (*i.e.*, creatine and pyruvate), each of which is taught in the prior art to be useful for the same purpose, to form a third composition (*i.e.*, creatine pyruvate) that is to be used for the very same purpose (see Office Action, ¶5). Contrary to the Examiner's allegation, Applicants submit that the creatine taught in Kaddurah-Daouk and Meisner (and optionally in Grant as an additive), and the pyruvate taught in Beale '469 and Beale '926 are not used for the same purpose. Kaddurah-Daouk relates to weight regulation, Meisner relates to wound healing, and Beale '469 and Beale '926 relate to muscle building (see discussion in the Response Under 37 C.F.R. § 1.116 filed on December 20, 2005, the Pre-Appeal Brief Conference Request filed on January 20, 2006, and the Amendment filed on May 8, 2006, all of which are incorporated by reference herein). One skilled in the art of weight regulation would have no motivation to apply or modify teachings that relate to wound healing or muscle building. Likewise, one skilled in the art of wound healing would have no motivation to apply or modify teachings that relate to weight regulation or muscle building. Nor would one skilled in the art of muscle building have motivation to apply or modify teachings that relate to weight regulation or wound healing. In addition, Applicants submit that the creatine taught in Kaddurah-Daouk and Meisner, and the pyruvate taught in Beale '469 and Beale

'926 are not used for treatment of the same type of body tissue, since bone and cartilage are different types of body tissues than muscle.

Applicants agree with the Examiner's observation that the amounts of creatine disclosed in Kaddurah-Daouk are for treatment of diseases other than a bone or cartilage condition, the wide range disclosed in Grant is for creatine and not creatine pyruvate, and the amount disclosed in Beale '469 and Beale '926 are for pyruvate and not creatine pyruvate. (See Office Action, ¶6). However, Applicants disagree with the Examiner's conclusion that "one of ordinary skill in the art would have reasonably expected that 1.4-284 mg of creatine pyruvate per day be useful for reducing, or ameliorating the symptoms of the disease." As discussed, above, the cited references relate to different technical fields and one skilled in the art would not have reasonably expected to treat the recited condition using a particular amount of a particular agent which was never mentioned in the cited references.

The Examiner alleges that the cited references meet the limitation "in need thereof" since the references "fairly suggested the usefulness of creatine pyruvate for treating osteoporosis or osteoarthritis." (See Office Action, ¶7). In response, Applicants respectfully submit that the Examiner's allegation is based on a misunderstanding of the applicable law. In *Jansen*, the court reasoned that the "need" must be recognized and appreciated by the subject even though it may be possible that the same need is satisfied without the subject knowing so. 342 F.3d at 1334. In order to render obvious the claimed subject matter, the case law makes it clear that the methods of Kaddurah-Daouk in view of Meisner, Grant, Beale '469, and Beale '926 must be practiced with the intent to achieve the objective stated in the preamble of claim 1, namely the objectives of treating at least one bone or cartilage condition. *Jansen v. Rexall*, 342 F.3d at 1333. This the references fail to do.

Kaddurah-Daouk discloses the administration of creatine to a subject who is desirous of regulating an imbalance of body weight or treating or preventing a body disorder related to weight gain or loss; Meisner discloses the administration of a composition comprising, *inter alia*, an anti-inflammatory substance such as creatine, to a subject who is desirous of accelerating the healing of wounds (cause unknown); Grant discloses the administration of a non-steroidal anabolic composition comprising, *optionally*, creatine, to a subject who is desirous of building and sustaining muscle mass; and Beale '469 and Beale '926 discloses the administration of pyruvate to a subject who is desirous of increasing lean body mass or muscle tissue (see discussion in the Response Under 37 C.F.R. § 1.116 filed on December 20, 2005 at pages 9-10, incorporated by reference herein). None of the references disclose, teach

or suggest the administration of creatine pyruvate, and further do not disclose, teach or suggest the administration of a substance (creatine pyruvate) to a subject who is desirous of having a bone or cartilage condition treated. Since the subjects of Kaddurah-Daouk, Meisner, Grant, Beale '469, and Beale '926 desire a type of treatment different than that desired by the subjects of amended claim 1, the references do not render obvious amended claim 1.

The Examiner also alleges that the claims are directed to an old and well known ultimate utility which is inherently disclosed in the prior art. (See Office Action, ¶8). In response, Applicants submit that the case law makes it clear that an obviousness rejection cannot be based on inherent disclosure in a prior art reference. *In re Spormann*, 363 F.2d at 448. There is no explicit suggestion of the claimed method (*i.e.*, the use of a particular amount of creatine pyruvate to treat an animal who is desirous of being treated for at least one bone or cartilage condition) in Kaddurah-Daouk, Meisner, Grant, Beale '469, and Beale '926, either alone or together, and silence of the references regarding the claimed method is not a suggestion, and cannot be used as a basis for a rejection under 35 U.S.C. § 103. *Id.*

Furthermore, Applicants respectfully submit that the case law cited by the Examiner (*i.e.*, *In re Swinehart*, 169 U.S.P.Q. 226, 229 (C.C.P.A. 1971)) is inapplicable to the rejection in the instant application. In *In re Swinehart*, the issue being appealed relates to the rejection of a claim for allegedly failing to particularly point out and distinctly claim the invention as required under 35 U.S.C. § 112, not 35 U.S.C. § 103. Thus, the holding and rationale used to evaluate the claim rejection in *In re Swinehart* is not applicable to the present rejection.

Even assuming that the Examiner is correct to reference the holding of *In re Swinehart* (which he is not), the portion of the case discussed by the Examiner pertains to the evaluation of novelty, not obviousness, as in the present case. As discussed above, "obviousness cannot be predicated on what is unknown," and thus, the Examiner's arguments are misplaced. *In re Spormann*, 363 F.2d at 448.

In addition, the Examiner alleges that the fact that Applicants have recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. (See Office Action, ¶9). As discussed above, none of the cited references disclose, teach or suggest the administration of creatine pyruvate to a subject. Nor does any one of the cited references disclose, teach or suggest the administration of creatine pyruvate to treat a bone or cartilage condition. Contrary to the Examiner's allegation, the claimed method being practiced and the administration of a particular amount of a particular agent, when neither the same agent or

amount is disclosed, taught or suggested in the cited references, is not “another advantage which would flow naturally from following the suggestion of the prior art.”

Finally, the Examiner alleges that hindsight reconstruction is necessary and proper and insists that there is suggestion and motivation in the cited reference to combine the references. (See Office Action, ¶¶10 and 11). Contrary to the Examiner’s allegation, the courts have made it clear that hindsight is never proper and should be avoided in applying the non-obviousness requirement. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1 U.S.P.Q.2d 1593 (Fed. Cir. 1987), *cert. denied*, 481 U.S. 1052 (1987). The fact that the Examiner needed to use five disparate references from which to pick and choose isolated disclosures without regard to the references as a whole is indicative of such improper hindsight reconstruction. As discussed above, there is no motivation to combine the teaching of references which relate to weight regulation (Kaddurah-Daouk), wound healing (Meisner), and muscle building (Grant, Beale ‘469 and Beale ‘926), and one skilled in the art would find no reasonable expectation of success to arrive at the claimed method using the recited agent at the particular amount.

For the foregoing reasons, the combination of Kaddurah-Daouk plus Meisner, Grant, Beale ‘469, and Beale ‘926 does not teach or suggest the method of amended claim 1.

**b. Amended Claim 22**

Regarding amended claim 22, none of the references disclose, teach or suggest the use of the recited amount of creatine pyruvate to promote growth and mineralization of bone or cartilage cells and tissues in a subject that is desirous of said promotion. The Examiner admits that Kaddurah-Daouk does not teach the employment of creatine pyruvate for promoting growth and mineralization of bone. (See Office Action, ¶4). As discussed above, Meisner, Grant, Beale ‘469, and Beale ‘926 do not cure the deficiency of Kaddurah-Daouk, because none of these references disclose, teach or suggest the use of creatine pyruvate or the administration of a substance (creatine pyruvate) to promote growth and mineralization of bone or cartilage cells and tissues, much less disclose, teach or suggest the use of creatine pyruvate at the recited amount to promote growth and mineralization of bone or cartilage cells and tissues in a subject who desires said promotion; and thus, do not provide the missing suggestion. Accordingly, the combination of Kaddurah-Daouk plus Meisner, Grant, Beale ‘469, and Beale ‘926 does not teach or suggest the method of amended claim 22.

**c. Amended Claim 23**

Regarding amended claim 23, none of the references disclose, teach or suggest the use of creatine pyruvate to improve acceptance and osseous integration of bone implants in a subject who is desirous of said improvement. The Examiner admits that Kaddurah-Daouk does not teach the employment of creatine pyruvate for improving acceptance and osseous integration of bone. (See Office Action, ¶4). As discussed above, Meisner, Grant, Beale '469, and Beale '926 do not cure the deficiency of Kaddurah-Daouk, because none of these references disclose, teach or suggest the use of creatine pyruvate or the administration of a substance (creatine pyruvate) to improve acceptance and osseous integration of bone implants, much less disclose, teach or suggest the use of creatine pyruvate at the recited amount to improve acceptance and osseous integration of bone implants in a subject who desires said improvement; and thus, do not provide the missing suggestion. In fact, none of the references ever mentioned a bone implant, much less a subject having such bone implant or the treatment of such subject. Accordingly, the combination of Kaddurah-Daouk plus Meisner, Grant, Beale '469, and Beale '926 does not teach or suggest the method of amended claim 23.

**d. Amended Claim 24**

Regarding amended claim 24, none of the references disclose, teach or suggest the use of creatine pyruvate to accelerate healing of a defect in bone or cartilage tissue caused by trauma or surgery in a subject who is desirous of said acceleration. The Examiner admits that Kaddurah-Daouk does not teach the employment of creatine pyruvate for accelerating healing. (See Office Action, ¶4). As discussed above, Meisner, Grant, Beale '469, and Beale '926 do not cure the deficiency of Kaddurah-Daouk, because none of these references disclose, teach or suggest the use of creatine pyruvate or the administration of a substance (creatine pyruvate) to accelerate healing of a defect in bone or cartilage tissue caused by trauma or surgery, much less disclose, teach or suggest the use of creatine pyruvate at the recited amount to accelerate healing of a defect in bone or cartilage tissue caused by trauma or surgery in a subject who desires said acceleration; and thus, do not provide the missing suggestion. Accordingly, the combination of Kaddurah-Daouk plus Meisner, Grant, Beale '469, and Beale '926 does not teach or suggest the method of amended claim 24.

In view of the foregoing, Applicants respectfully submit that the rejection is in error and respectfully request the Examiner withdraw the rejection.



**CONCLUSION**

Applicants respectfully request entry of the remarks made herein into the file history of the present application. Withdrawal of the Examiner's rejections and an allowance of the application are earnestly requested. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Respectfully submitted,

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